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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/448,330	11/22/1999	STEPHEN A. JOHNSTON	UTSD:681	4922

7590 10/02/2002

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HILL, MYRON G

ART UNIT	PAPER NUMBER
1648	12

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/448,330	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 March 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 34,36,37,41- 65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 34,36,37,41- 65 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

This office action is in response to Amendment B, paper #11, filed 3/19/02. The following claims are pending: 34, 36, 37, 41- 55 and 56- 65.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 36, 37, and 41- 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34 and 56- 65 are rejected because it is not clear if the claim is drawn to a product or intended to be a method. It is assumed for this office action that the claim is a product claim, of the type "product-by-process." Claim 57- 60 and 62- 65 recite the limitation "DNA". There is insufficient antecedent basis for this limitation in the claim because there are two different recitations of the word "DNA" in each of claims 34 and 36.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 36, 41- 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. "Synthetic DNA" is considered new matter. While literal support is not required for amendments to the claims, clearly stated disclosure of the idea is. Throughout the specification, reference is made to fragments of genomic DNA from pathogens (or cDNA made from RNA genome pathogens), for example see Figures 6 and 10. Applicant is requested to point to disclosure in the original filed specification that contemplates any synthetic DNA because support for these claims is not apparent to the Examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34, and 57- 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Pietromonaco (PNAS 1990, Vol 8⁷, pages 1811- 1815).

Pietromonaco teaches an antibody obtained by administering to an animal one clone from an expression library from a selected cell type (abstract).

Claim Rejections - 35 USC § 102/ 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 41, 42, and 56- 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fynan (PNAS 1993, Vol 90, pages 11478- 11482).

Fynan teaches an antibody against influenza made by genetic immunization (abstract).

Fynan teaches an antibody that meets the limitations of the claimed antibody which is described by the process used to make it. However, the production process does not confer any distinguishing characteristics upon the resulting antibody. Therefore, any antibody directed against the same antigen reasonably appears to be the same or similar as the antibody made by Applicant's process.

Claims 34, 43, and 56- 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Conry (Cancer Research 1994 Vol. 54, pages 1164- 1168).

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Conry teaches an antibody against a cancer antigen (abstract, Figure 1, and Table 4).

Claims 34, 43, and 56- 60 are drawn to an antibody which is described by the process used to make it. However, the production process does not confer any distinguishing characteristics upon the resulting antibody. Therefore, any antibody directed against the same antigen reasonably appears to be the same or similar as the antibody made by Applicant's process.

Claims 34,36, 37, 41, 44- 50, 52- 55, 56, and 61- 65 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Butman (US 4,950,589).

Claims 36 and 37 are drawn to a kit for detecting a pathogen comprising an antibody that can detect an antigen of the pathogen, an amount of pathogen, and immunodetection means.

Butman teaches a kit to detect *Listeria monocytogenes* that comprises an antibody reactive against a protein of the pathogen, and shows a western blot where a suitable amount of the pathogen is detected by immunodetection means (Figure 2, columns 5- 10, and claims 7 and 8). It would be obvious to make antibodies to other pathogens bacterial pathogens for use in kits with the expectation of success.

Butman teaches an antibody that meets the limitations of the claimed antibody which is described by the process used to make it. However, the production process does not confer any distinguishing characteristics upon the resulting antibody.

Therefore, any antibody directed against the same antigen reasonably appears to be the same or similar as the antibody made by Applicant's process.

The Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Myron G. Hill
Patent Examiner
October 1, 2002

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1600